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10/840,205	05/06/2004	Christopher E. Banas	6006-157	7254

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EXAMINER

GANESAN, SUBA

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 2/24/2010 have been fully considered but they are not persuasive. Applicant argues that Drasler teaches that sutures may be used with an intravascular tubular member but defines no suture openings through which the sutures could be threaded. This is not persuasive; fig. 12 clearly shows the stent element connected via sutures. The sutures must penetrate the graft, creating suture openings in the process. Suture openings are considered a product-by-process limitation; since a suture has been threaded through the graft, there is a suture opening.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims **1-3, 13-15, and 17-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (WO 01/74274 A2) (Palmaz) in view of Casey, II et al. (Pub. No.: US 2004/0019375) (Casey) further in view of Drasler (6,287,335).
2. Palmaz discloses an implantable medical graft, comprising: a. a generally tubular body member comprising a film selected from the group consisting of metallic and pseudometallic materials (page 17, lines 1-7); and b. at least a portion of the body member having a plurality of undulations formed in walls of the body member by a

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support arranged in any manner as is known in the art of stent fabrication (page 5, lines 16-20, also see fig. 2 and 10, noting structural members 22 are thicker than the interstitial webs 24), and microperforations (e.g. Figs. 2-3 and 8A-8C).

3. However, Palmaz does not disclose the support arranged **specifically** as having continuous circumferential undulations. Casey teaches a vascular graft structure with continuous circumferential undulations and undulation-free sections (see fig. 1) resulting in a prosthetic graft with strong and flexible walls. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the graft of Palmaz with areas of continuous circumferential undulations as taught by Casey for the purpose of providing a strong and flexible graft wall.

Palmaz discloses several methods of fabricating the disclosed stent/graft, including deposition and etching. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to combine a thin film deposited graft with unitary structural support members as taught by Palmaz with a specific pattern of structural support (ie an undulating structure) as taught by Casey, since doing so would be a substitution of the structural members of Palmaz with the undulating structure of Casey, both designs arriving at the same purpose: providing a stronger graft. Such a substitution of one known equivalent element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Palmaz in view of Casey lacks suture openings on an end of the graft. Drasler teaches the use of such openings (fig. 12A) for the purpose of securing an end support to the graft. Therefore it would have been obvious to one of ordinary skill in the art at the time the

invention was made to have utilized sutures to secure an end support to the combination of Palmaz and Casey. One of ordinary skill in the art would have further been motivated to provide suture openings to provide specific placement of sutures aid a surgeon in anchoring the prosthetic to a native blood vessel.

With respect to claim 2, Palmaz discusses selectively placing patterns of openings (figs. 8A-C). One of ordinary skill in the art would understand that the pattern can be selectively placed to achieve varying sites for cellular migration. Such a modification of Palmaz would have occurred using known methods and yielding predictable results. With respect to claims 4 and 18, Palmaz teaches portions of the graft without support members (see fig. 3).

With respect to claim 17, Palmaz in view of Casey discloses the circumferential corrugations as claimed. The resultant combination would be fully capable of bending in excess of 180 degrees about the longitudinal axis, since Palmaz discloses thin film deposition, which results in a thin and flexible prosthesis, and Casey teaches the use of corrugations to increase flexibility (fig. 1).

4. Claim **12** is rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (WO 01/74274 A2) (Palmaz) in view of Casey, II et al. (Pub. No.: US 2004/0019375) (Casey) and Drasler (6,287,335) as applied above and further in view of Van Schie et al (6,974,471 B2) (Van Schie).

5. Palmaz discloses an implantable medical graft as above. However, Palmaz does not disclose at least one suture member integrally extending along the longitudinal axis

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and through suture holes. Van Schie teaches an implantable medical graft comprising at least one suture member integrally extending along the longitudinal axis and through suture holes (e.g. Figs 4 and 6). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of at least one suture member integrally extending along the longitudinal axis and through suture holes, as taught by Van Schie, to an implantable medical graft as per Palmaz, such that “the device can be curved in situ to fit the curved lumen” as found in Van Schie (col. 1, lines 44-52).

6. Claims **6-7, 9-10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (WO 01/74274 A2) (Palmaz) in view of Casey, II et al. (Pub. No.: US 2004/0019375) (Casey) and Drasler (6,287,335), further in view of Kula et al (6,325,825 B1) (Kula).

7. Palmaz in combination with Casey and Drasler teaches an implantable medical graft as above. However the combination lacks the thickness of the undulating regions as less than that of the non-undulating regions. Kula teaches an implantable medical graft having thicker ends, which correspond to the non-undulating regions of Palmaz/ Casey (col. 4, lines 60-66). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of an implantable medical graft having thicker ends, as taught by Kula, to an implantable medical graft as per Palmaz/ Casey, in order to “protect the artery and any plaque from abrasion that may be caused by the stent 10 ends during insertion of the stent 10. The modification

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also may provide increased radio-opacity at the ends of the stent 10. Hence it may be possible to more accurately locate the stent 10 once it is in place in the body” as found in Kula (col. 4, lines 60-66).

Regarding claim 7 Palmaz/ Casey in further view of Kula fail to disclose the **specific** thicknesses of the claimed regions. However, Palmaz discloses that the thickness of the microperforated material is approximately 10 micrometers (page 21, lines 13-14). Palmaz also discloses that the undulations may be formed by a “subtractive” method (Fig. 10). The reduction of the undulation region relative to the non-undulated region would result in a thickness of the thinner region *about* 3-7 micrometers.

8. With respect to claims 9 and 10, Palmaz/ Casey/Kula fail to disclose the suturing openings as cruciform or generally Y-shaped slots. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to make the slots these shapes. Applicant has not disclosed that these shapes provides an advantage, is used for a particular purpose, or solve a stated problem, and therefore appear to be a matter of obvious design choice. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the holes of Drasler or the claimed slots because both allow for the passage of sutures. Furthermore such shaped holes for sutures are known in the art (Moser U.S. Pat. No. 5725556).

Therefore, it would have been obvious to one of ordinary skill in the art to modify the cited references to obtain the invention as specified in claims 9 and 10. Please note that

the Applicant may have intended to claim the microperforations as cruciform or generally Y-shaped slots.

9. Claim **11** is rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (WO 01/74274 A2) (Palmaz) in view of Casey, II et al. (Pub. No.: US 2004/0019375) (Casey) and Drasler (6,287,335) as applied above and further in view of Banas et al. (5,749,880) (Banas).

10. Palmaz discloses an implantable medical graft as above. However Palmaz does not disclose the implant having barbs. Banas teaches an implantable medical graft having projecting barb members (col. 14, lines 48-54). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of projecting barb members, as taught by Banas, to an implantable medical graft as per Palmaz, in order to aid in anchoring to the target blood vessel wall, as in Banas (col. 14, lines 48-54).

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G./
Examiner, Art Unit 3774

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738

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